UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,732	12/20/2004	Robert M Lorence	18025-PCTUS	3190

7590 09/24/2008

Lewis J. Kreisler
Legal Department
930 Clopper Road
Gaithersburg, MD 20878

EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
09/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,732	LORENCE, ROBERT M	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,12,17,21-23,26-32 and 34* is/are pending in the application.

4a) Of the above claim(s) *31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 9, 12, 17, 21-23, 26-30, and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/29/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6, 9, 12, 17, 21-23, 26-32, and 34 are pending in the application.

2. In the prior action, mailed on January 29, 2008, claims 1-6, 9, 12, 17, 21-23, 26-32, and 34 were pending; with claims 31 and 32 withdrawn from examination; and claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 rejected.

3. In the Response of July 29, 2008, claim 17 was amended.

4. Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 are under consideration.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on July 29, 2008 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

6. **(Prior Rejection- Withdrawn)** Claim 17 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for depending from cancelled claim 16. In view of the amendment of the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were rejected under 35 U.S.C. 103(a) as obvious over Lorence R (hereinafter "Lorence A", WO 99/18799A1) in view of Lorence R. (hereinafter "Lorence B," WO 94/25627A1), and, further in light of the teachings of Curtis et al. (U.S. 7083794) and Castracane et al. (U.S. 2005/0074901). Applicant traverses the rejection on two (related) grounds.

The first argument is an assertion that those of ordinary skill in the art would not have been motivated to use the indicated method for desensitization against the therapeutic viruses because those in the art would not have expected such desensitization to maintain or improve the efficacy of the target therapeutic. In particular, the Applicant notes that the teachings of Castracane indicate that, while it was known that increasing dosages of drugs can induce tolerance, such also negates the therapeutic benefits of the drugs.

The argument is noted, but is not found persuasive. The teachings of Castracane indicate that such negating tolerance is achieved through increasing the amount of the agent administered over time. However, the fact that the reference teaches the problem indicates that those in the art would have considered such in determining the number and dosages of desensitizing dosages administered to the patients. In view of such, and of the teachings of the Lorence references indicating that desensitizing dosages were nonetheless useful in limiting the toxicity of the administered virus, it would have been obvious to those of ordinary skill in the art to adjust the amounts and number of desensitizing dosages so as to minimize the side effects of the virus,

while retaining the therapeutic benefits of such. Those in the art would have had a reasonable expectation that desensitization could be used in the administration of the virus based on the data of Example 20 of the Lorence A reference, showing that desensitization occurred with the administration of prior (though not reduced) administrations, but indicating that the patients to whom the virus was administered benefited from the administrations.

Thus, the teachings in the art merely indicate that those in the art would have known to be careful to adjust the desensitizing treatments to avoid the nullification of the therapeutic benefits. Nonetheless, the teachings in the Lorence references suggest the use of desensitization administrations as part of the therapy, and indicate that inclusion of such steps may be performed without a loss of therapeutic benefit. Applicant's argument is therefore not found persuasive.

The second argument in traversal is an argument of unexpected results because those of ordinary skill in the art would not have expected the desensitization process of the present claims to retain or improve the therapeutic utility of the administered virus. However, for the reasons indicated above, it is not accepted that those in the art would have expected that use of desensitizing dosages according to the claims would of necessity result in a loss of therapeutic benefit. As such, the assertion of unexpected results on this basis is not found persuasive.

The rejection is therefore maintained for the reasons above, and the reasons of record.

9. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were rejected under 35 U.S.C. 102(a) as anticipated by Pecora et al. (J. Clinical Oncology May 2002, Vol. 20, no. 9, pp. 2251-2266) or, in the alternative, under 35 U.S.C. 103(a) as obvious over in view of Lorence R. ("Lorence B"- WO 94/25627A1), and further in light of the teachings of Curtis and Castracane. The Applicant traverses this rejection on the same grounds as asserted with respect to the rejection over Lorence A and B above. For the same reasons as indicated above with respect to that rejection, the Applicant's arguments are not found persuasive over the rejection. In particular, it is noted that, like in Lorence A, the teachings of Pecora indicate that the administration of the virus achieved therapeutic reduction in tumors despite the use of escalating (i.e. desensitizing) dosages. See e.g., page 2264. The rejection is therefore maintained for the reasons above and the reasons of record.

10. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lorence R ("Lorence C"- WO 0062735A2) in view of Lorence B, and further in light of the teachings of Curtis and Castracane. The Applicant traverses this rejection on the same grounds as asserted with respect to the rejection over Lorence A and B in view of Curtis and Castracane above. For the same reasons as indicated above with respect to that rejection, the Applicant's arguments are not found persuasive over the restated rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-12 of the copending Application No. 10,547,654 in view of the teachings of Lorence R (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane. Applicant's arguments regarding the failure of the copending claims to teach the administration of at least three sequentially increasing doses is noted. However, the reference does teach the use of a desensitizing dose, and the argument ignores the teachings of the additional secondary references. It is noted that this is an obviousness type rejection. Thus, the precise limitations of the present claims need not be specifically identified in the present claims if they represent obvious variations of the copending claims. The Applicant further traverses this rejection on substantially the same grounds as asserted with respect to the obviousness rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. **(Prior Rejection- Maintained)** Claims 11-6, 9, 12, 17, 21-23, 26-30, and 34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 14-15, 18-19 of copending Application No. 10,548,057 in view of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane. The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness and double patenting rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5-17 of copending Application No. 10,700,143 in view of Lorence R. (WO 94/25627A1), and further in light of the teachings of Curtis and Castracane. Although claims 9-10 and 15 of the copending application have been cancelled, such does not overcome the rejection. The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness and double patenting rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 118, 119, 120, 133, 149, 150 of copending Application No. 10,167,652 n view of Lorence R. (WO 94/25627A1), and further in light of the teachings of Curtis and Castracane. The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness and double patenting rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims over the teachings of the copending claims 157, 166, 174, 197-200, 201, 210, 217, 230, 231, 232 of copending Application No. 09,958,809, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane. It is noted that the copending claims have been allowed, although have not yet been issued as a patent. The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness and double patenting rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. **(Prior Rejection- Maintained)** Claims 1-6, 9, 12, 17, 21-23, 26-30, and 34 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the teachings of the claims 1-27 of U.S. Patent No. 7,056,689, in view of the teachings of Lorence R. (WO 0062735A2- the Lorence C reference), and further in light of the teachings of Curtis and Castracane. The Applicant traverses this rejection on substantially the same grounds as asserted with respect to the obviousness and double patenting rejections above. The arguments are not found persuasive for the reasons indicated in response to those arguments.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claims are allowed.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648